

REMARKS

Claims 1, 6, 11-16, and 29-42 were examined in this case. All claims stand rejected under 35 U.S.C. § 112, first paragraph, and claims 1, 6, and 31-42 stand rejected under 35 U.S.C. § 102. Each of these issues is addressed below.

Amendments

Claim 1 has been amended. This amendment finds support in original claim 14, now canceled. New claim 43 has been added. This claim finds support in the specification, for example, at page 17, line 13. These amendments add no new matter.

For the record, Applicants do not agree with the current rejections and reserve the right to pursue all canceled subject matter in this or a future, related application.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 6, 11-16, and 29-42 stand rejected under 35 U.S.C. § 112, first paragraph based on written description. As applied to the present claims, this rejection should be withdrawn. The Office states that:

Claims 11-16 recite a structural protein from any AAV serotype distinguished by specific cleavage sites. The claims do not specify a specific AAV with these cleavage sites but any AAV with these cleavage sites. Applicants have not demonstrated that they were in possession of this broad class of proteins. Furthermore, the specification discloses a single example of structural mutants, which comprise insertions that have increased infectivity and can also form particles. As demonstrated in table 3, insertion at amino acid 587 results in increased infectivity in B16F10 cells.

On this issue, Applicants first point out that the amended claims are limited to AAV2, obviating the first basis for the rejection. In addition, the claims now require that the mutation be an insertion.

With respect to the second basis for the rejection, it is pointed out that the case law

nowhere states that patent applicants must demonstrate in their specification the workability of a given species in order for it to satisfy the written description requirement.

All that is required is that an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the claimed invention (*Vascath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1989)) and, if a genus is claimed, that it be described by disclosure of relevant, identifying structural and functional characteristics (*Regents of University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002)). Both of these requirements are met by the present claims.

Independent claim 1, from which all other claims depend, now requires that the structural protein be from AAV2 and that the protein include an insertion mutation positioned at one of 11 possible consecutive amino acid positions at 7 possible sites within the capsid protein. In addition to this structural requirement, the claim also requires that the mutated structural protein be capable of particle formation, a relevant, identifying functional characteristic.

There can be no question that the invention of amended claim 1 is clearly described in Applicants' specification. This claim refers to specific insertions in the structural protein of AAV2 which are supported by the specification, in particular, on page 11, lines 10-18 (see also page 6, lines 34-38), Example 2 on page 17 in combination with Table 1 on page 18, page 22 concerning the expression of P1 on the capsid surface, Example 9 on page 23 concerning the binding of AAV2 capsid insertions to integrin-expressing cells, and Example 5 on page 19 concerning a P1 mutation in VP3 in combination with (a) Example 7 on page 20 and Table 2 on page 22, (b) Example 10 on page 24 and Table 3 on page 26, (c) Example 11 on page 27, and (d) Example 12 on page 28.

Such descriptions satisfy the written description requirement, and this rejection

should be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1, 6, and 31-42 stand further rejected, under 35 U.S.C. § 102, as being anticipated by Mamounas et al. (WO 97/38723). Current independent claim 1 now includes the limitations of previous claim 14, a claim determined to be patentable over Mamounas. This rejection is therefore moot and may be withdrawn.

Overlapping Subject Matter

Applicants bring to the Office's attention the fact that the present application is believed to contain and claim subject matter that is overlapping with subject matter claimed in Bartlett, U.S. Patent Application 10/038,972.

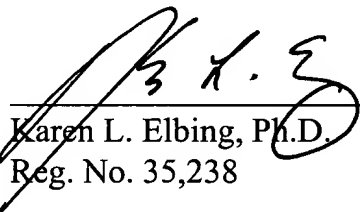
CONCLUSION

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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